

**REMARKS****The Rejection of Claims 30-61 Under 35 U.S.C. §112, second paragraph**

Independent claims 30, 53 and 58 stand rejected under 35 U.S.C. §112, second paragraph because the Examiner finds it “unclear whether or not a gel or suspension that comprises at least 75% by weight of said saccharide (as recited in b) is not considered a medicament which comprises at least 75% by weight of said saccharide (as recited in a).”

Applicant respectfully submits that the claims in their present form are clear. There is no apparent ambiguity in the expression of the compositions of the medicaments described in a) and b) of these claims. It is clear that a gel or suspension comprising at least 40% by weight of said saccharide can, of course, include more than 40% of the saccharide and that a gel or suspension comprising at least 75% of the saccharide falls within the scope of both a) and b). Applicant hereby amends claims 38 and 39 to emphasize that gels or suspensions comprising at least 50% and at least 75% by weight of the saccharide are claimed. It is submitted that that one of skill in the art could understand the metes and bounds of the claims and if the Examiner continues to assert otherwise, explanation of the basis for an asserted lack of clarity is respectfully requested. In view of Applicant’s belief in the clarity of these independent claims, it is respectfully requested that the rejection of claims 30, 53, and 58 be withdrawn.

Applicant presumes, although the Examiner has not explicitly so stated, that claims 31-52 and 54-57 are rejected under 35 U.S.C. §112, second paragraph due to dependence on independent claims 30, 53 or 58. In view of Applicant’s belief in the clarity of the independent claims, it is respectfully requested that the rejection of these claims be withdrawn as well.

The Examiner further rejects independent claim 59 and dependent claims 60-61. Although not explicitly stated in the Office Action, Applicant presumes that independent claim 59 is likewise rejected for the reasons described for independent claims 30, 53 and 58, and Applicant submits that this claim and claims 60-61 which depend therefrom are clear and respectfully requests that the rejection of these claims be withdrawn as well.

Dependent claim 36 stands separately rejected under 35 U.S.C. §112, second paragraph. Claim 36 is hereby cancelled.

**The Rejection of Claim 58 Under 35 U.S.C. §112, first paragraph**

Independent claim 58 is hereby cancelled. Applicant submits that this rejection is therefore moot and requests withdrawal of the rejection.

**The Rejection of Claims 53-57 Under 35 U.S.C. §103(a) Over Woitun et al. (DE 1959402 A)**

Independent claim 53 and claims 54-57 are rejected as obvious over Woitun et al. (DE 1959402 A).

Independent claim 53 describes pharmaceutical compositions for vaginal application comprising a saccharide and less than  $10^5$  bacteria per dosage, wherein the composition includes a) at least 75% by weight of the saccharide or b) wherein the composition is a gel or suspension and includes at least 40% by weight of the saccharide.

In contrast, the Woitun et al. reference teaches various compositions of which only one, described in Example III, appears to be for vaginal application. Applicant notes that the sole composition described in Example III does not appear to include a saccharide. Thus, the reference does not appear to teach or suggest all aspects of the present claims.

The Examiner states that "it is obvious to prepare Woitun et al.'s composition in different percent or amounts of saccharide or bacteria based on factors such as the type and severity of the symptom or condition and type and age of the individual treated."

Applicant submits there is simply no basis for this assertion. One of skill in the art has no motivation to adjust the percent or amounts of saccharide or bacteria given the teachings of Woitun et al. On the contrary, the Woitun et al. reference refers to 2-(5-nitro-2-furyl)-4-hydroxy-thieno 3,2-d pyrimidines as the active ingredients in the described compositions. No reference to bacteria content of the Woitun et al. compositions is apparent. It appears that this element is contributed by Applicant's specification and the rejection therefore is based on the use of impermissible hindsight.

Applicant submits that there is no basis for the present obviousness rejection and no prima facie case of obviousness is established. Withdrawal of the rejection and allowance of the claims is respectively requested.

**The Rejection of Claims 30-48, 51-52 and 59-61 Under 35 U.S.C. §103(a) Over Ozmen et al. (Turkish Journal of Medical Sciences (1998), 28(2), pp. 171-173)**

Claims 30-48, 51-52 and 59-61 stand rejected over Ozmen et al. (Turkish Journal of Medical Sciences (1998), 28(2), pp. 171-173).

Independent claims 30 and 59 describe methods including administering a medicament including a saccharide and less than  $10^5$  bacteria per dosage, wherein the medicament includes a) at least 75% by weight of the saccharide or b) wherein the composition is a gel or suspension and includes at least 40% by weight of the saccharide.

The Examiner states that “[t]he difference between applicant’s claimed method and the method of Ozmen et al. is the percent or amount of saccharide in the composition.” (Paper No.20080813, p.10, last para.) It is asserted that “it is obvious to prepare and administer Ozmen et al.’s compositions comprising different percent or amounts of saccharide and bacteria based on factors such as the type and severity of the symptom or condition and type and age of the individual treated.” (Paper No.20080813, p.10, last para.)

Applicant notes that administration of bacteria appears to be asserted as the basis of therapeutic effects seen using methods and compositions described in Ozmen et al. For example, Ozmen et al. states that they “conducted a randomized trial to compare the effects of three different treatment modalities (oral metronidazole, oral metronidazole plus locally administered lyophilised lactobacilli, and only locally administered lyophilized lactobacilli) on the course of bacterial vaginosis.” (p.171, right column) The Ozmen et al. reference describes administration of doses of *Lactobacillus acidophilus* “containing at least  $10^7$  to  $7 \times 10^8$  viable microorganisms...” (p.172, left column, 1<sup>st</sup> full para.) This is in contrast to the present claims which describe administration of a medicament which includes less than  $10^5$  bacteria per dosage. It is noted that this dosage is considered to be substantially free from bacteria, as stated in the present specification, p.6, lines 16-25. Applicant submits that there is no reasonable basis for an assertion of obviousness since the Ozmen et al. reference directly teaches away from compositions and methods which are substantially free from bacteria. One of skill in the art would find no motivation to reduce the therapeutic dose of microorganisms of Ozmen et al. by 100-fold or more.

Applicant submits that there is no basis for the present obviousness rejection and no prima facie case of obviousness is established with regard to independent claims 30 and 59. In view of Applicant's belief as to the allowability of the independent claims, dependent claims 31-48, 51-52 and 60-61 are likewise submitted to be allowable. Withdrawal of the rejection and allowance of the claims is respectively requested.

**The Rejection of Claims 49-50 Under 35 U.S.C. §103(a) Over Ozemen et al.**  
**(Turkish Journal of Medical Sciences (1998), 28(2), pp. 171-173)**  
**in Combination with Lin et al. (US 2003/0017207 A1)**

Dependent claims 49 and 50 stand rejected over Ozemen et al. (Turkish Journal of Medical Sciences (1998), 28(2), pp. 171-173) in combination with Lin et al. (US 2003/0017207 A1)

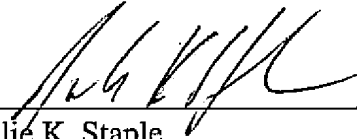
As described above, Applicant submits that there is no basis for the obviousness rejections based on the Ozmen et al. reference and no prima facie case of obviousness is believed to be established with regard to independent claim 30. In view of Applicant's belief as to the allowability of the independent claim, dependent claims 49-50 are likewise submitted to be allowable. Withdrawal of the rejection and allowance of the claims is respectively requested.

**Summary**

Claims 36, 37 and 58 are hereby cancelled. Claims 38 and 39 have been amended. In view of these amendments and the remarks hereinabove, Applicant believes the pending application is in condition for allowance or in better condition for appeal and entry of this amendment is respectfully requested. Applicant's below signed representative may be contacted to discussion this application at the telephone and/or facsimile numbers provided below.

Dated: Oct. 13, 2008

Respectfully submitted,

By 

Julie K. Staple

Registration No.: 50,434

GIFFORD, KRASS, GROH, SPRINKLE,

ANDERSON & CITKOWSKI, P.C.

2701 Troy Center Drive, Suite 330

Post Office Box 7021

Troy, Michigan 48007-7021

(734) 913-9300

Attorney for Applicant